

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of : Kukolj, George et al) Art Unit: To be assigned
U.S. Appln. No. : To be assigned) Examiner: To be assigned
Confirmation No. : To be assigned
U.S. Filing Date : February 27, 2004
Title of Invention : SELF-REPLICATING RNA MOLECULE FROM HEPATITIS C
VIRUS
Attny. Docket No. : 13/083-3-D2

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

February 27, 2004

TRANSMITTAL LETTER FOR INFORMATION DISCLOSURE STATEMENT

Sir:

Transmitted herewith concerning the subject application is an Information Disclosure Statement (Form 1449A/B) under 37 C.F.R. §§1.56 and 1.97, as more specifically described herein below. Copies of cited references can be found in prior application number 10/309,561, filed on December 4, 2002.

☒ 1.97(b). This Statement is being filed: i) within three (3) months of the filing date of a national application other than a continued prosecution application under 33 C.F.R. §1.53 (d); ii) within three (3) months of the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in an international application; iii) before the mailing of a first Office action on the merits; or iv) before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. §1.114.

☐ 1.97(c). This Statement is being filed after the time period specified in 37 C.F.R. §1.97(b), but before the mailing date of: i) a final action under 37 C.F.R. §1.113, ii) a notice of allowance under 37 C.F.R. §1.311, or iii) an action that otherwise closes prosecution in the application. This Statement is being accompanied by:

☐ A statement as specified in 37 C.F.R. §1.97(e) [see below]; or

☐ The fee set forth in 37 C.F.R. §1.17(p).

☐ The Commissioner is hereby authorized to charge payment of the \$180.00 fee set forth in 37 C.F.R. §1.17(p) to Deposit Account No. 02-2955.

☐ 1.97(d). This Statement is being filed after the period specified in 37 C.F.R. §1.97(c) but on or before payment of the issue fee. This Statement is accompanied by a statement as specified in 37 C.F.R. §1.97(e) [see below] and the fee set forth in 37 C.F.R. §1.17(p).

☐ 1.97(e).

☐ Each item of information contained in the instant information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to the filing of the instant information disclosure statement; or

☐ No item of information contained in the instant information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this certification after making reasonable inquiry, no item of information contained in the instant information disclosure statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three (3) months prior to the filing of the instant information disclosure statement.

☐ The fee set forth in 37 C.F.R. §1.17(p).

☐ The Commissioner is hereby authorized to charge payment of the \$180.00 fee set forth in 37 C.F.R. §1.17(p) to Deposit Account No. 02-2955.

☐ 1.704(d). Each item of information contained in the accompanying information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, which communication was not received by any individual designated in section 1.56(c) more than thirty (30) days prior to the filing of the accompanying information disclosure statement.

☒ The Commissioner is hereby authorized to charge payment of any additional filing fees required under 37 C.F.R. §1.16 and any patent application processing fees under 37 C.F.R. §1.17, or credit any overpayment of same, to Deposit Account No. 02-2955.

Triplicate copies of this form are enclosed.

Respectfully submitted,

Susan K. Pocchiari

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Susan K. Pocchiari

Susan K. Pocchiari, Reg. No. 45,016

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| Substitute for form 1449A/PTO PATENT DOCUMENTS SUBMITTED BY APPLICANT | | | | Complete If Known | |
| | | | | Application Number | To be assigned |
| | | | | Filing Date | February 27 2004 |
| | | | | First Named Inventor | Kukolj, George |
| | | | | Group Art Unit | To be assigned |
| | | | | Examiner Name | To be assigned |
| Sheet | 1 | of | 5 | Attorney Docket Number | 13/083-3-D2 |

| U.S. PATENT DOCUMENTS | | | | | | |
|-----------------------|-------------|----------------------|--------------------------------------|--|--|---|
| Examiner Initials | Cite No. | U.S. Patent Document | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Number | Kind Code ² (if known) | | | |
| | AUS1 | 20020142350 | | Kukolj, George | 10-3-2002 | |
| | AUS2 | 20030148348 | | Kukolj, George | 08-07-2003 | |
| | AUS3 | | | | | |
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| FOREIGN PATENT DOCUMENTS | | | | | | | | |
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| Examiner Initials | Cite No. | Foreign Patent Document | | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T |
| | | Office | Number | Kind Code (if known) | | | | |
| | AF1 | | WO 98/04008 | | Motorola Inc. | 29-01-1998 | | <input type="checkbox"/> |
| | AF2 | | WO 98/39031 | | Washington University | 11-09-1998 | | <input type="checkbox"/> |
| | AF3 | | WO 00/66623 | | Boehringer Ingelheim (Canada) Ltd. | 09-11-2000 | | <input type="checkbox"/> |
| | AF4 | | WO 01/89364 A2 | | Washington University | 29-11-2001 | | <input type="checkbox"/> |
| | AF5 | | | | | | | <input type="checkbox"/> |
| | AF6 | | | | | | | <input type="checkbox"/> |
| | AF7 | | | | | | | <input type="checkbox"/> |
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| Substitute for form 1449B/PTO NON-PATENT DOCUMENTS SUBMITTED BY APPLICANT | | | | Complete If Known | |
| | | | | Application Number | To be assigned |
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| | | | | First Named Inventor | Kukolj, George |
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| OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS |
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| Examiner Initials | Cite No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | T |
|-------------------|----------|--|--------------------------|
| | AO1 | FOURNIER, SUREAU et al.; In vitro infection of adult normal human hepatocytes in primary culture by hepatitis C virus; J. Virol.; 1998, V. 79; 2367-2374 | <input type="checkbox"/> |
| | AO2 | GRAKOU, WYCHOWSKI et al.; Expression and Identification of Hepatitis C Virus Polyprotein Cleavage Products; J. Virol.; 1993, V. 67, No. 3; 1385-1395 | <input type="checkbox"/> |
| | AO3 | HIJIKATA, MIZUSHIMA et al.; Two Distinct Proteinase Activities Required for the Processing of a Putative Nonstructural Precursor Protein of Hepatitis C Virus; J. Virol.; 1993, V. 67, No. 8; 4665-4675 | <input type="checkbox"/> |
| | AO4 | BARTENSCHLAGER, AHLBORN-LAAKE et al.; Nonstructural Protein 3 of the Hepatitis C Virus Encodes a Serine-Type Proteinase Required for Cleavage at the NS3/4 and NS4/5 Junctions; J. Virol.; 1993, V. 67, No. 7; 3835-3844 | <input type="checkbox"/> |
| | AO5 | REED, XU et al.; Phosphorylation of the Hepatitis C Virus NS5A Protein In Vitro and In Vivo: Properties of the NS5A-Associated Kinase; J. Virol.; 1997, V. 71, No. 10; 7187-7197 | <input type="checkbox"/> |
| | AO6 | KHROMYKH, WESTAWAY; Subgenomic Replicons of the Flavivirus Kunjin: Construction and Applications; J. Virol.; 1997, V. 71, No. 2; 1497-1505 | <input type="checkbox"/> |
| | AO7 | BEHRENS, GRASSMANN et al.; Characterization of an Autonomous Subgenomic Pestivirus RNA Replicon; J. Virol.; 1998, V. 72, No. 3; 2364-2372 | <input type="checkbox"/> |
| | AO8 | MIZUTANI, KATO et al.; Characterization of Hepatitis C Virus Replication in Cloned Cells Obtained from a Human T-Cell Leukemia Virus Type 1-Infected Cell Line, MT-2; J. Virol.; 1996, V. 70, No. 10; 7219-7223 | <input type="checkbox"/> |
| | AO9 | MOSER, TRATSCHIN et al.; A Recombinant Classical Swine Fever Virus Stably Expresses a Marker Gene; J. Virol.; 1998, V. 72, No. 6; 5318-5322 | <input type="checkbox"/> |
| | AO10 | IKEDA, SUGIYAMA et al.; Human hepatocyte clonal cell lines that support persistent replication of hepatitis C virus; Virus Research; 1998, V. 56; 157-167 | <input type="checkbox"/> |
| | AO11 | DASH, HALIM et al.; Transfection of HepG2 Cells with Infectious Hepatitis C Virus Genome; Amer. J. Pathology; 1997, V. 151; 363-373 | <input type="checkbox"/> |

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| OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS |
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| Examiner Initials | Cite No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | T |
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| | AO1 | KIM, MORGENSTERN et al.; Hepatitis C virus NS3 RNA helicase domain with a bound oligonucleotide: the crystal structure provides insights into the mode of unwinding; Structure; 1998, V. 6; 89-100 | <input type="checkbox"/> |
| | AO2 | YAN, LI et al.; Complex of NS3 protease and NS4A peptide of BK strain hepatitis C virus; A 2.2 A resolution structure in a hexagonal crystal form; Protein Science; 1998, V. 7; 837-847 | <input type="checkbox"/> |
| | AO3 | YAO, HESSON et al.; Structure of the hepatitis C virus RNA helicase domain; Nature Structural Biology; 1997, V. 4, No. 6; 463-467 | <input type="checkbox"/> |
| | A04 | ITO, MUKAIGAWA et al.; Cultivation of hepatitis C virus in primary hepatocyte culture from patients with chronic hepatitis C results in release of high titre infectious virus; J. Gen. Virol.; 1996, V. 77; 1043-1054 | <input type="checkbox"/> |
| | A05 | YOO, SELBY et al.; Transfection of a Differentiated Human Hepatoma Cell Line (Huh7) with In Vitro-Transcribed Hepatitis C Virus (HCV) RNA and Establishment of a Long-Term Culture Persistently Infected with HCV; J. Virol.; 1992, V. 69, No. 1: 32-38 | <input type="checkbox"/> |
| | AO6 | AGO, ADACHI et al.; Crystal structure of the RNA-dependent RNA polymerase of hepatitis C virus; Structure; 1999, V. 7; 1417-1426 | <input type="checkbox"/> |
| | AO7 | BLIGHT, KOLYKHALOV et al.; Efficient Initiation of HCV RNA Replication in Call Culture; Science; 2000, V. 290; 1972-1974 | <input type="checkbox"/> |
| | AO8 | BRESSANELLI, TOMEI et al.; Crystal structure of the RNA-dependent RNA polymerase of hepatitis C virus; PNAS; 1999, V. 96, No. 23; 13034-13039 | <input type="checkbox"/> |
| | AO9 | CHO, HA et al.; Crystal Structure of RNA Helicase from Genotype 1b Hepatitis C Virus; J. Biol. Chemistry; 1998, V. 273, No. 24; 15054-15052 | <input type="checkbox"/> |
| | AO10 | GALE JR., KORTH et al.; Evidence that Hepatitis C Virus Resistance to Interferon is Mediated through Repression of the PKR Protein Kinase by the Nonstructural 5A Protein; Virology; 1997, V. 230; 217-227 | <input type="checkbox"/> |
| | AO11 | GRAKOU, MCCOURT et al.; A second hepatitis C virus-encoded proteinase; Proc. Natl. Acad. Sci. USA; 1993, V. 90; 10583-10587 | <input type="checkbox"/> |

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| | AO1 | KWONG, KIM et al.; Hepatitis C virus NS3/4A protease; Antiviral Research; 1998, V. 40; 1-18 | <input type="checkbox"/> |
| | AO2 | LANFORD, SUREAU et al.; Demonstration of in Vitro Infection of Chimpanzee Hepatocytes with hepatitis C Virus Using Strand-Specific RT/PCR; Virology; 1994, V. 202; 606-614 | <input type="checkbox"/> |
| | AO3 | LESBURG, CABLE et al.; Crystal structure of the RNA-dependent RNA polymerase from hepatitis C virus reveals a fully encircled active site; Nat. Struc. Biolo.; 1999, V. 6, No. 10; 937-943 | <input type="checkbox"/> |
| | AO4 | LOHMANN, KORNER et al.; Replication of Subgenomic Hepatitis C Virus RNAs in a Hepatoma Cell Line; Science; 1999, V. 285; 110-113 | <input type="checkbox"/> |
| | AO5 | LOHMANN, KORNER et al.; Mutations in Hepatitis C Virus RNAs Conferring Cell Culture Adaptation; J. Virology; 2001, V. 75, No. 3; 1437-1449 | <input type="checkbox"/> |
| | AO6 | LOVE, PARGE et al.; The Crystal Structure of Hepatitis C Virus NS3 Proteinase Reveals a Trypsin-like Fold and a Structural Zinc Binding Site; Cell; 1996, V. 87, 331-342 | <input type="checkbox"/> |
| | AO7 | SHIMIZU, PURCELL et al.; Correlation between the infectivity of hepatitis C virus in vivo and its infectivity in vitro; Proc. Natl. Acad. Sci. USA; 1993, V. 90, 6037-6041 | <input type="checkbox"/> |
| | AO8 | YANAGI, ST. CLAIRE et al.; In vivo analysis of the 3' untranslated region of the hepatitis C virus after in vitro mutagenesis of an infectious cDNA clone; Proc. Natl. Acad. Sci. USA; 1999, V. 96, 2291-2295 | <input type="checkbox"/> |
| | AO9 | | <input type="checkbox"/> |
| | AO10 | | <input type="checkbox"/> |
| | AO11 | | <input type="checkbox"/> |

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| | AO1 | GOU, JU-TAO et al.; Effect of Alpha Interferon on the Hepatitis C virus Replicon; J. Virol.; 2001, 75(18):8516-8523 | <input type="checkbox"/> |
| | AO2 | HIJIKATA, MAKOTO et al.; Gene mapping of the putative structural region of the hepatitis C virus genome by in vitro processing analysis; Proc. Natl. Acad. Sci.; 1991, 88:5547-5551 | <input type="checkbox"/> |
| | AO3 | KIM, DONG WOOK et al.; C-Terminal Domain of the Hepatitis C Virus NS3 Protein Contains an RNA Helicase Activity; 1995, 215(1):160-166 | <input type="checkbox"/> |
| | AO4 | KIM, J.-E. et al; Subcellular localization of hepatitis C viral proteins in mammalian cells; Arch Virol.; 1999, 144:329-343 | <input type="checkbox"/> |
| | AO5 | KIM, J.L. et al; Crystal Structure of the Hepatitis C Virus NS3 Protease Domain Complexed with a Synthetic NS4A Cofactor Peptide; Cell; 1996, 87:343-355 | <input type="checkbox"/> |
| | AO6 | KRIEGER, NICOLE, et al; Enhancement of Hepatitis C Virus RNA Replication by Cell Culture-Adaptive Mutations; J. of Virol.; 2001, 75(10):4614-4624 | <input type="checkbox"/> |
| | AO7 | | <input type="checkbox"/> |
| | AO8 | | <input type="checkbox"/> |
| | AO9 | | <input type="checkbox"/> |
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